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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/576,951 | 05/24/2000 | Katherine L. Molnar-Kimber | A-7733 | 5248 |

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03/13/2003

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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/13/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,951

Applicant(s)

MOLNAR-KIMBER ET AL

Examiner

Mary (Molly) E. Ceperley

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-40 and 42-46 is/are allowed.
- 6) ☒ Claim(s) 41 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1) The information disclosure statement filed December 20, 2002 fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file. The STATEMENT UNDER 37 C.F.R. 1.97(e) which states that "no item of information contained in the Second Supplemental Information Disclosure Statement was known to any individual designated in 37 C.F. R. 1.56© more than three months prior to the filing of said Second Supplemental Information Disclosure Statement appears to conflict with the fact that the references cited in this disclosure statement are referred to in the August 01, 2002 response which response is dated more than three months prior to the filing of the Second Supplemental Information Disclosure Statement. However, the references cited in the Second Supplemental Information Disclosure Statement have been cited on accompanying form PTO-892 and have been considered by the examiner.

2) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3) Claim 41 and 47 are again rejected under 35 USC 112, first paragraph, for the reason stated in paragraph **4)** of the August 20, 2002 Office action.

Applicants' arguments filed December 20, 2002 have been fully considered but they are not persuasive. Independent of the reason for submitting the Bycroft and Molnar-Kimber declarations (Remarks, page 5, first full paragraph), these declarations establish that one skilled in the art would not previously have expected that monoclonal antibodies to rapamycin could be prepared. This expectation is relevant to both obviousness and enablement issues. As set forth in the declarations, although rapamycin is structurally similar to FK-506 it does not function similarly. As stated at page 7 of the Molnar-Kimber Declaration under 37 C. F. R. 1.132:

"...there are significant structural differences between natural rapamycin and FK-506 and these structural differences result in divergent biological activities. Hence, the inhibitory effects of FK-506 and rapamycins on the generation of monoclonal antibodies were expected to be very different."

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Therefore an obviousness rejection based on the structural similarity of rapamycin to FK-506 could not stand (Remarks, page 5, last paragraph). However, a related issue under 35 USC 112, first paragraph, is that given the fact that it would be unexpected that monoclonal antibodies to rapamycin could be prepared, how does one skilled in the art practically prepare such antibodies? In the instant specification, applicants have provided an enabling written description of the preparation of antibodies using specific immunogens. Applicants' reliance upon the Lederman et al patent (Remarks, page 7) for the position that the claims of the instant invention need not be limited to the use of specific immunogens appears to be misplaced. In distinction to the instant invention where there is a basic question of whether or not one skilled in the art would be expected to be able to produce antibodies to rapamycin, there is no such question regarding the protein epitope of the Lederman et al patent i.e., one skilled in the art would *expect* that antibodies could be produced to the claim 1 antigen of Lederman et al.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "obtainable using" is different in scope from the term --obtained using--. The term --obtained using-- is a positive limitation that requires that the MAb be made using the recited immunogen. The term "obtainable" requires only that the MAb be capable of being produced using the recited immunogen. Thus, the exact scope of this claim is unclear. This rejection could be overcome by substituting --obtained using-- for "obtainable".

6) Claims 33-40 and 42-46 are allowed.

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7) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

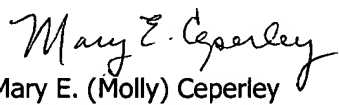
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

March 7, 2003


Mary E. (Molly) Ceperley
Primary Examiner
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